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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,713	06/20/2003	Takeshi Koizumi	5328-12	7563

27799 7590 11/30/2005

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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,713	KOIZUMI ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04, 10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1, 4-11 are pending in the instant application. Claims 2 and 3 have been cancelled. Claims 6-11 are newly added. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. They represent the complete being presently applied to the instantly examined claims. Response to arguments follow. This action is FINAL.

Priority

2. Acknowledgment is made of applicant's prior foreign application, Japan 2002-003912. It is noted that applicants are not claiming priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Japan on 01/10/2002, since the United States application was filed more than twelve months thereafter. ***Withdrawn Rejections***

3. The rejections of claims 1-5, under 35 U.S.C. 112, second paragraph, made in section 4, pages 2-3 of the previous office action, is withdrawn in view of the amendment to the claims.

4. The rejections of claims 1-5, under 35 U.S.C. 101, made in section 5, page 3 of the previous office action, is withdrawn in view of the amendment to the claims.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is drawn to an oligonucleotide that comprises no more than 40 bases and has a quantity of a more numerous base of G and C that accounts for at least 50% of said combined G and C content and a quantity of a more numerous base of A and T that accounts for at least 50% of a combined content of A and T. The claim is indefinite because it is unclear if the claim requires that 50% of the oligonucleotide be G and C and the other 50% be A and T *or* if the claim intends for at least 50% of the oligonucleotide to be G and C content and A and T content because it is not possible for an oligonucleotide to have greater than both G and C content and A and T content. It is unclear because an oligonucleotide can not have a more numerous base is G and C and A and T and with each GC and AT content requiring at least 50% because this would equate to a greater than 100% . As the claim is written, it is unclear how one would obtain an oligonucleotide with greater than 100% G, C, A , and T content when only 100% content is possible. Furthermore it is unclear what "a more numerous base" means and how this limits the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-5, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by (J. Virology, Dec 1993, p. 7118-7124). It is noted that this rejection was previously presented in section 6, page of the previous office action and has been rewritten to accommodate the amendment to claims 1, 4-5 and newly added claims 9-10.

With regard to claim 1, 4, 5, 9 and 10, Sorensen et al. teach a method that comprises PCR amplification by providing a biotinylated provirus-specific primer and a partly degenerate arbitrary primer (instant claim 4) with a fixed 3' end which will hybridize (instant claim 5) within a statistically defined range in the cellular DNA flanking the provirus (see 1st column, 3rd paragraph, page 7118) (figure 1 and 2). The primers used for amplification and hybridization have a biotin coupled to the 5' end of the primer (see figure 1A and 1C) and comprise a phosphate group at the 5' terminus (instant claim 1 and 5). An oligonucleotide will have a phosphate group present at the 5' terminus, by definition of its structure. The biotin coupled to the 5' end of the primer comprises a linker (phosphate bond between the biotin the primer) (instant claim 10). A linker is broadly interpreted to mean anything that couples or connects two objects and therefore the primer by Sorenson et al. comprises a biotin conjugated to the 5' end of the primer by a phosphate bond, which is a linker.

Response to Arguments

9. The response asserts on page 6, 2nd paragraph of the response mailed, 09/06/2005, that Sorensen et al. does not disclose any PCR primer with a compound attached at the 5' terminus as recited in claims 1 and 4-5. This response has been thoroughly reviewed but not found persuasive. Claims 1 and 4-5 require that a PCR primer comprises a compound at the 5' terminus which can be a phosphate group. By nature of the structure of DNA and RNA, a primer

at the 5' end of primer or oligonucleotide, will comprise at the 5' terminus of a phosphate group and therefore claims 1 and 4-5 are anticipated by Sorensen et al.

The response asserts on page 6, 4th paragraph that Sorensen et al. does not recite PCR that is either one of asymmetric and degenerative when biotin is attached to the PCR primer and that there is no disclosure that Sorensen et al. that a primer which biotin is conjugated to the 5' terminus is suitable for asymmetric or degenerative PCR. This response has been thoroughly reviewed and not found persuasive. Claim 9 requires a method of amplifying a target DNA by providing "a" PCR primer that comprises a biotin at the 5' terminus and amplifying the target DNA by either asymmetric or degenerative PCR. Sorensen et al. discloses degenerative PCR amplification using a PCR primer that comprises a biotin at the 5' terminus, see page 7118, 1st column, last paragraph. Therefore, Sorensen et al. anticipates claim 9.

The response asserts on page 6, last paragraph that Sorensen et al. does not disclose the use of a linker to conjugate biotin to the primer. This response has been thoroughly reviewed but not found persuasive. Sorensen et al. teach a primer with a biotin group attached to the 5' terminus of the primer. A linker is broadly interrupted to mean something that couples or connects two objections. A phosphate bond connects the biotin to the 5'end of the primer and therefore comprises a linker.

For these reasons, Sorenson et al. anticipates claims 1, 4-5, 9 and 10.

10. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Genome Research, 1997, vol. 7, pp. 389-398).

With regard to claims 6-8, Liu et al. teach asymmetric PCR by providing primers (see

table 1) to amplify specific alleles. Liu et al. teach primer concentrations of .1 μM and .05 μM concentrations (see figure 3) (asymmetric PCR). The primers taught by Liu et al. comprise an oligonucleotide that comprises 10 bases that comprise 100% G and C content at the 5' end of the primer sequence (see table 1). It is noted that claim 7 requires a more numerous base of G and C that accounts for at least 50% and a more numerous base of A and T that accounts for at least 50% content for the oligonucleotide (not the primer), which is indefinite as discussed in section 6 above. Since it is impossible to obtain both a G and C content of at least 50% and an A and T content of at least 50% , which would equal greater than 100%, the claim has been broadly interpreted to require a G and C content of at least 50% or a A and T content of at least 50% and therefore Liu et al. teach primers with an oligonucleotide at the 5' terminus that comprise a G and C content of 100% (see table 1).

11. Claims 5, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Skouv et al. (US Patent 6303315 Oct 16, 2001).

With regard to claim 5, Skouv et al. teach a method for hybridization by providing a LNA probe (oligonucleotide probe) which can be labeled with rhodamine, digoxigenin, Texas Red and exemplify a label at the 5' end of the LNA probe (see column 5, lines 60-67 and column 8, lines 63-67 and column 9, lines 1-5, column 10, lines 1-36 and table 1-1).

With regard to claim 10 and 11, Skouv et al. teach a method of hybridization by providing a LNA probe (oligonucleotide probe) with a 5' biotin label with a hydrocarbon group of 4 carbon atoms as linker (instant claim 11) (see column 32, table 1-1, note) and hybridizing the 5' biotin labeled LNA probe to the DNA (see column 32, lines 5-25).

Conclusion

12. No claims are allowable.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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